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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,768	01/16/2002	Shen-Chun Kuo	CD01352	7782

24265 7590 07/11/2003

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT PAPER NUMBER

1624

DATE MAILED: 07/11/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

10/050,768

Applicant(s)

KUO, SHEN-CHUN

Examiner

Venkataraman Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-15 is/are rejected.
- 7) ☒ Claim(s) 9 and 16-24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Applicants' response, which included amendment to claims 1, 16 and cancellation of claims 25-28, filed on 4/25/2003, is made of record.

Claims 1-24 are now pending.

In view of applicants' response, the following apply.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. Recitation of " a reagent that oxidizes  $\text{NH}_2$  to  $\text{NZ}$ " in claim 3 is indefinite as one trained in the art would <sup>not</sup> know which amino group is being referred to. Note there are three amino groups in compound of formula II but there is no teaching as to which one is being referred to.

Applicants' argument to overcome this rejection is not persuasive. Contrary to applicants' urging specification has no guidance as to which  $\text{NH}_2$  is being referred to and one trained in the art has guess and speculate as applicants have done in their remarks. Hence the claim is vague and unclear. Therefore, the rejection is maintained.

one trained in the art

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1624

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for  $\text{Bu}_4\text{I}/\text{H}_5\text{IO}_6$  as oxidizing/cyclizing agent, does not reasonably provide enablement for any or all oxidizing/cyclizing agent generically embraced in the claim language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record.

Applicants' argument to overcome this rejection is not persuasive.

First of all, the rejection is a scope of enablement rejection not an enablement issue. Applicants have cited case laws, which are pertinent to enablement as whole not to scope of enablement issues raised by the examiner.

Secondly, the rejected claims are process claims. Applicants are claiming a process for making known compound temozolomide or its analogs. Therefore the critical reagent/step should be fully enabled. The scope of oxidizing/cyclizing agent reads on any or all oxidizing/cyclizing agent those yet to be discovered for the said reaction for which there is no enabling disclosure.

Thirdly, as recommended by the applicants' one trained in the art were to identify those agents which might function as oxidizing/cyclizing agent and do experimentation to arrive at a process for making temozolomide or its analogs, it is not clear how could that be applicants' claimed process when there is no enabling teaching. None of the case laws cited by the applicants support such a contention that an oxidizing/cyclizing

Art Unit: 1624

agent identified by one trained in the art can be deemed as applicants' invention. If these agents are that obvious then applicants' process can be deemed as obvious variant.

Hence this rejection is proper and is maintained.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for  $\text{Bu}_4\text{I}$  as soluble iodide, does not reasonably provide enablement for any or all iodide generically embraced in the claim language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record.

Applicants' argument to overcome this rejection is not persuasive.

To repeat again, the scope of the claim as recited includes any or all iodide for which there is no enabling disclosure. Applicants are asserting in the specification that the iodide functions as catalyst for the reaction and therefore the iodide is a critical limitation for the process. Without knowing what iodide is included or excluded, one need to extensive experimentation to arrive at a suitable iodide given the fact that solubility of iodide would also to be considered in the choice of the iodide. Prior art does not teach how to select an iodide suitable for the instant reaction scheme and the example recited in the specification is limited to  $\text{Bu}_4\text{NI}$  which is known to be soluble in organic solvent. Hence the specification is not adequately enabled to make the product of formula I with iodide other than  $\text{Bu}_4\text{NI}$ .

In addition, as noted above, none of the case laws cited by the applicants state that the critical element of the reaction not taught by the invention, if identified and enabled by one trained in the art, it should be deemed as applicants' invention.

Hence this rejection is also maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. J. Org. Chem. 62: 7288-7294, 1997 for reasons of record. To repeat:

Wang et al. teaches the compound of formula shown in claim 25. See page 7289, scheme 3, compound 14a, 14b, 14c. See page 7292, column 2 for the experimental details.

This rejection is same as made in the previous office action except the cancelled claim 27 is excluded from the rejection. Applicants have not offered any traversal as why this rejection is not applicable. Hence these rejections are maintained.

***Claim Rejections - 35 USC § 103***

Claims 10, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chabala et al EP 0113,570.

This rejection made in the previous office action is withdrawn.

Art Unit: 1624

### ***Claim Objections***

Claims 9 and 16-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claims would be allowed since specific process embraced in these claims are not taught or suggested by the art of record or from a search in the relevant art area.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

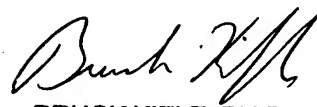
Art Unit: 1624

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
V. Balasubramanian

07/9/2003

  
BRUCK KIFLE, PH.D.  
PRIMARY EXAMINER